smiths medical
bringing technology to life

Smiths Medical ASD
1265 Grey Fox Rd
St. Paul MN 55112

URGENT MEDICAL DEVICE FIELD CORRECTIVE ACTION

CADD® Administration Sets with Flow Stop

Affected Devices: **CADD® Administration Sets with Flow Stop**

Type of Action: Field Corrective Action

Date: 9-May-2016

Attention: Clinicians who oversee the use of the CADD® Administration Sets with Flow Stop and Distributors thereof.

Affected devices:

The following Product Re-order Numbers for devices with a device expiration date on or before March 2021 are affected by this issue.

Product Re-order Number				
21-7321-01	21-7321-24	21-7322-01	21-7322-24	21-7323-24
21-7324-01	21-7324-24	21-7333-24	21-7336-01	21-7336-24
21-7339-01	21-7339-24	21-7359-01	21-7359-24	21-7383-01
21-7383-24	21-7390-01	21-7390-24	21-7391-01	21-7391-24
21-7394-01	21-7394-24	21-7395-24		

Customer FSN

Dear Valued Customer,

The purpose of this letter is to advise you that Smiths Medical has initiated a voluntary global Field Corrective Action for CADD® Administration Sets with Flow Stop, within the affected dates listed above.

REASON FOR FIELD CORRECTIVE ACTION:

Smiths Medical has become aware that under delivery of medication may occur on CADD® Administration Sets with Flow Stop. **Only those CADD® Administration Sets with Flow Stop with Product Re-order numbers listed above and that expire on or before March 2021 are affected by this Action.**

This Field Corrective Action is being performed with the knowledge of the appropriate regulatory authorities.

RISK TO HEALTH:

CADD® Administration Sets with Flow Stop have the potential to impact flow rate when used with a variety of CADD® ambulatory infusion pumps, which may result in under delivery of medication. Our risk analysis concluded that there is a very remote probability that under delivery may occur resulting in patient harm, as all possible levels of patient harm were evaluated to be rare.

Our test data indicates that under infusion has the potential to contribute to an average of an additional 5.2% under delivery beyond the $^{+/-}$ 6% stated in the Operator's Manual for the CADD® pumps. If drug under delivery occurs, patients may not receive their full volume of medication in the prescribed timeframe.

CADD® Ambulatory Infusion Pumps are used for a variety of infusion therapies. Potential health consequences from an under delivery will depend on the patient condition, the therapy involved, the degree of under delivery that occurs, and possibly the time to discovery.

Our risk analysis identified the following possible serious adverse health consequences with a very remote probability of occurrence:

1) Inadequate symptom control (dependent on therapy being delivered). For example: Increase in pain or increase in cardiac symptoms (heart rate, rhythm, blood pressure);

2) Inadequate treatment (dependent on therapy being delivered). For example: Sub-therapeutic doses delivered of medication in which a specific volume needs to be infused such as antibiotics, chemotherapy, or nutritional therapy.

Smiths Medical has not received any reports of deaths or serious injuries related to the under delivery with the CADD® Administration Sets with Flow Stop.

INSTRUCTIONS TO CUSTOMERS:

PLEASE TAKE THE FOLLOWING ACTIONS TO HELP US PROPERLY EXECUTE THIS FIELD CORRECTIVE ACTION

There is no need to return your product.

1. For Distributors: If you are a distributor and you have distributed CADD® Administration Sets with Flow Stop to your customers, please immediately notify them of this Field Corrective Action. Skip to step 5 below.

2. For Clinicians: Prior to use of the product, review the product reorder number and the expiration date on product labeling for all CADD® Administration Sets with Flow Stop devices in your inventory to determine if the device(s) are affected by this Field Corrective Action.

   Outer Carton

   If you are looking at the outer carton, the picture below depicts where you can locate the re-order number and the expiration date:

Primary Sterile Pack

If you are looking at the primary sterile pack that contains the device, the pictures below depicts where you can locate the re-order number and the expiration date:

Product re-order number is visible from the clear side of the packaging:	Expiration date is visible from the reverse side of the packaging:
	

3. For Clinicians: As stated in the Operator's Manual for the CADD® pumps, there are a number of factors that may contribute to under delivery of therapy. Please continue to monitor for under delivery when utilizing the CADD® Administration Sets with Flow Stop. For your reference, please refer to the excerpt from the Operator's Manual for CADD® pumps regarding delivery accuracy and other factors that can affect delivery accuracy:

> System delivery inaccuracies beyond $^{+/-}$6% may occur as a result of back pressure or fluid resistance, which depends upon temperature, drug viscosity, catheter size, extension set tubing (for example, microbore), in-line components (such as filters and needless access connectors), and placing the infusion reservoir and/or pump above or below the level of the patient. System delivery inaccuracy may result in under or overdelivery of medication.

4. For Clinicians: If you are a clinician, please consider whether your patients and their caregivers should be informed of this field corrective action.

5. For Distributors and Clinicians: Review and complete the Field Corrective Action Confirmation Form and return it to Smiths Medical by Fax to +44 (0)1233 722153 or by email to FCA.Response@smiths-medical.com within 10 days of receipt of this letter. The form must be returned to us even if you do not have any CADD® Administration Sets with Flow Stop sets in your possession.

If you have any questions regarding this notification, please contact Smiths Medical Customer Service Department at +44 (0)845 850 0445.

Should you experience under delivery of the identified product contact the Smiths Medical Global Complaints Department at +00 800 76 48 47 00.

Please report any issues with these products to Smiths Medical's Global Complaint Department at +00 800 76 48 47 00 or globalcomplaints@smiths-medical.com.

Smiths Medical is committed to providing quality products and service to its customers. We apologize for any inconvenience this situation may cause.

Sincerely,

Tim Giguere
Manager, Quality Systems
Smiths Medical ASD, Inc.

Jennifer C. Meng
Director Government Relations and Compliance
Smiths Medical ASD, Inc.

Enclosures: Attachment 1 – Field Corrective Action Confirmation Form